

United States Department of Agriculture
Food Safety and Inspection Service
Dr. Sally Stratmoen
Chief Equivalence Section
International Policy Staff
Washington, D.C. 20251

FAX: 011.202.720.7990



landbouw, natuurbeheer
en visserij

Your letter of	your reference	our reference	date
JAN 17 2002		VVA/02.926/18	MARCH 14 2002
re:		extension no.	enclosures
FSIS Inspection		+31-70-3785399	

Dear Dr Stratmoen,

Introduction

Herewith the Dutch response to the draft final audit report, concerning an on-site audit of the Dutch meat inspection system performed by the Food Safety and Inspection Service. This audit, carried out by Dr. Choudry, took place from 1 to 24 October 2001. On 24 October there was a closing discussion between the inspector, representatives of the Dutch government and a representative of the European Commission. A copy of this response, together with the draft report, will be sent to the European Commission. I received your draft report on 17 January 2002. On 12 February we discussed the report on the telephone. We then confirmed that we would respond within 60 days of receipt of the report. This written response conforms with what we proposed on 12 February.

General

In general I would comment that the draft report takes a very negative tone, which I do not consider appropriate. The Dutch meat inspection system is of high quality, meets internationally accepted standards and guarantees safe production of meat. I do not think this is adequately reflected in the report.

Several references are made in the report to minor shortcomings in such a generalised way as to give an incorrect impression that they are commonplace. I would request that you correct this impression. This applies to a greater extent to the comments made concerning Classical Swine Fever; you are aware that the Dutch pig stock, following the epidemic of '97-'98, and again since the summer of 1998 is free of Classical Swine Fever in accordance with internationally accepted standards (OIE).

As a last general point I would note that matters treated in this report as being unsatisfactory, such as HACCP, SSOP, and the RVV laboratory, were found to be in order during the previous audit. I attribute this to a different interest and approach on the part of the auditor; I consider this lack of uniformity undesirable.

Clarifications with regard to the draft report

Please see below a number of clarifications which can be used to correct and revalue the report.

Ministry of Agriculture,
Nature Management and
Fisheries
Vondings- en Veterinaire
Aangelegenheden
Veterinaire Handel en
Controle
Beuldenhousweg 73
Postal Address: 20401
2500 EK DEN HAAG
Telephone: 070-3785399
Fax: 070-3786142
Telegram Address: Landvis
32440 Lavin

IPS/643
BW 3/19/02

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- Classical Swine fever does not occur in the Netherlands. The Dutch pig stock has been free from classical swine fever in accordance with the internationally accepted standards of the OIE since the summer of 1998 (see pp. 1 and 11).
- Following the names of Dr. Luuk van Duijn, Dr. Ate Jelsma, Dr. Ron Dwinger and Dr. Henk Keukens 'LNV' should be replaced by 'RVV' (see pp. 4 and 18).
- The abbreviation of the RVV laboratory is LRVV (see p.8).
- Under the heading "reporting positive results" on page 12, the correct procedure is as follows: If animal samples are found to be positive, the AID launches an investigation into the cause. Animals from which positive samples are taken are seized and destroyed. In the case of illegal growth promoters additional sampling must be carried out. The number of animals to be sampled equals the root +1 of the number of animals present. If positive samples are subsequently detected in one or more animals, all the animals present on the holding must be sampled. Only those animals from which positive samples are taken are destroyed. Fines can be imposed as a penalty (see p. 12).
- For the testing of carcasses for the presence of *Salmonella*, the sponge method, and not the cork bore method, is used in the targeted and screening analysis (instructions RE-29 and RE-30) (see page 16).
- At the meeting in Brussels it was not Dr. Willem Droppers who was present, but Dr. Star van der Meijs, Veterinary Board, at the Dutch Embassy for the EU in Brussels (see page 19).
- The methods used in the Netherlands in the inspection of calves of up to six months of age, were already explained in detail in a letter to the FSIS of 4 January 2001, ref. VVM004060/RF.
- Microbiological tests on ready-to-use products for *Salmonella* and *Listeria* are carried out annually by the RIVM. This was also explained at length in the letter to the FSIS of 4 January 2001, ref. VVM004060/RF. In an extra letter, which I will send you the coming days, I shall provide you with information about the amount of ready-to-use products which were tested for *Salmonella* and *Listeria* in 2001.
- In laboratory testing of residues in cattle the *State Institute for Quality Control of Agricultural Products* (RIKILT) and the *RVV Laboratory* (LRVV) test various types of control samples for each method, ranging from blank sample, through samples with additive to certified reference samples (trace elements). However, there are no suitable reference materials available for very many of the components stipulated in the National Plan. In other situations it is impossible to prepare control samples which are sufficiently stable to test a method over a sustained period. It is thus impossible to follow the same system for all components when setting up a secure system. Even the FAPAS organisation, which offers proficiency testing within Europe for securing investigation methods has only a limited range in the field of residues of growth promoters and veterinary medicines.
- In the Netherlands the laboratories impose requirements for all quantitative analysis methods for the recovery for the samples with additive analysed within the series. These requirements are set down in the method of analysis and it also specifies what action is required if there is an aberrant result within a series. If a method is used whereby deuterated internal standards are added to every sample, then often only a single requirement is set for the minimum traceable percentage to reach the desired limit of quantification. This last approach is used specifically for the determination of illegal growth promoters using GC-MS and LC-MS. Unique identifica-

tion in accordance with EU criteria at the level of the MRPL (minimum required performance level) is in that case more important than measuring the exact concentration. Laboratory samples taken from animals to be analysed for the presence of residues of unauthorised substances are usually analysed within 72 hours. Samples taken in the slaughter phase are frozen after receipt at -18 °C until the time of analysis. This analysis will be completed within a period of 6 to 13 weeks. For a number of components (OCs, PCBs, heavy metals) keeping samples for a long time does not present problems. For critical components (antibiotics, organophosphorous compounds) samples are only kept for a short time (from 4 to a maximum of 6 weeks).

Adjustments to the Dutch system in response to the FSIS audit

As already mentioned in the introduction, the recent audit was the first to examine the Dutch HACCP and SSOP methodology in such specific detail. In the teleconference we discussed the fact that it would have been more scrupulous to have announced this in advance. On the other hand, we must admit in all fairness that we found a number of your inspector's comments extremely useful. This will assist the Netherlands, and possibly also the EU, in the further development of the systems in question. In fact we will implement the following adjustments.


- If meat production companies are producing for the US they will be subject to daily inspections by the RVV, even where there is a second and third shift working in a multi-shift system. If meat production companies are not producing for the US, inspections may be less frequent.
- Once per month the team leader (or another RVV supervisor) will visit the responsible veterinary practitioner and inspect part of the company's operations (e.g. pre-operational sanitation procedures or operational sanitation, a CCP, another aspect of the HACCP, work in the cutting line, etc.).
- The companies will adapt their HACCP systems (clear description of the risk analysis, validation of the HACCP by third parties and meticulous description, monitoring, correction and verification of CCPs). The RVV will run weekly checks on the implementation of the HACCP. The verification consists of three parts: physical checks, monitoring of company official controlling the CCPs, documentary checks of the reports and corrective actions.
- The RVV will carry out daily checks (verification) on the "pre-operational sanitation" (cleaning before work begins) and "operational sanitation" (cleanliness during work) in the slaughter and cutting processes. The verification consists of several parts: first verifying whether the company has carried out the checks and completed the operational checklists and secondly whether one's own findings, following checks with the aid of a company checklist of various parts of the business, corresponds to the findings of the company itself, and finally whether corrective measures have been effectively implemented. Checks on meat product companies can be less frequent, but still more often than once per month.
- RVV officials must supervise the maintenance of zero tolerance and the prevention of product contamination (for example by paying attention to cleaning the intestine conveyor belt with water at 82°C, cleaning and decontamination of the sticking knife after bleeding of each pig, adapting the procedure and the application of the treatment of meat which has fallen on the floor). Immediate action is required whenever faecal contamination is found.

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- The inspection regulations must be followed meticulously. The following points merit special attention:
 - ⇒ cutting into the Masseter muscle of calves (do not cut through the aponeurosis but through the muscle);
 - ⇒ cutting into the mandibular lymph glands of pigs and calves;
 - ⇒ palpation of liver in pigs and calves and lungs in calves;
 - ⇒ palpation of lungs in pigs (if intended for human consumption);
 - ⇒ palpation of lymph glands of liver and lungs in pigs.
- The companies will institute a "pre-shipment" check of the CCPs (last documentary control before the product leaves the company premises). The RVV must monitor the procedure, implementation and reporting
- When sampling carcasses the samples must be taken randomly. The industry will develop a procedure to guarantee this. The RVV official can use this procedure or develop his or her own procedure.
- The RVV official (and not the industry) will take the samples for the monitoring of meat products intended for export to the USA. Checks will be made to ensure that the animal species stated on the label corresponds to the animal species in the product.
- The RVV laboratory in Wageningen will direct the targeted and screening analysis for *Salmonella*. The same laboratory will also direct the verification analysis for faecal contamination.
- In the laboratory analysis for residues, the RIKILT can make greater use than hitherto of unknown check samples for testing the analysis process. This relates particularly to testing by other inspection institutions active in a similar field and with which there is periodic consultation.
- Results of control samples and recovery experiments must be accurately established by the RVV laboratory and by RIKILT and follow up actions arising from the identified aberrations will be recorded.
- RIKILT and the RVV laboratory will each use a uniform system for the management and registration of the use or creation of reference standards for residue analysis.
- RIKILT will carry out the analyses of residues in samples of animal origin within a storage time limit, which is known not to affect the original residue concentration. The storage time limit of samples for analysis for organophosphorous compounds will be no longer than 6 weeks.

I assure that you will refer to the factual inaccuracies in your final report and that you will report our other findings in an accompanying letter. I look forward to our continued collaboration with interest.

Yours sincerely,



Dr. Frits Plummers
Chief Veterinary Officer